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Characteristics of women screened for a contraceptive intravaginal ring study in Kisumu, Kenya, 2014

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Abstract

Background—HIV antiretroviral-based intravaginal rings with and without co-formulated contraception hold promise for increasing HIV prevention options for women. Acceptance of and ability to correctly and consistently use this technology may create challenges for future ring-based microbicide trials in settings where this technology has not been introduced. We examined baseline factors associated with enrolling in a contraceptive intravaginal ring study in Kisumu,

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Kenya and describe notional acceptability (willingness to switch to a contraceptive ring based solely on information received about it).

Methods—Demographic, psychosocial, and behavioral eligibility screening of women 18–34 years was undertaken. Testing for pregnancy, HIV, and other sexually transmitted infections (STIs) was also conducted. We compared enrollment status across groups of categorical predictors using prevalence ratios (PR) and 95% confidence interval (CI) estimates obtained from a log-binomial regression model.

Results—Out of 692 women pre-screened April to November 2014, 463 completed screening, and 302 women were enrolled. Approximately 97% of pre-screened women were willing to switch from their current contraceptive method to use the intravaginal ring exclusively for the 6–month intervention period. Pregnancy, HIV, and STI prevalence were 1.7%, 14.5%, and 70.4% respectively for the 463 women screened. Women 18–24 (PR=1.47, CI 1.15–1.88) were more likely to be enrolled than those 30–34 years of age, as were married/cohabitating women (PR=1.62, CI 1.22–2.16) compared to those separated, divorced, or widowed. In adjusted analyses, sexual debut at less than 17 years of age, one lifetime sexual partner, abnormal vaginal bleeding in the past 12 months, condomless vaginal or anal sex in the past 3 months, and not having a sexual partner of unknown HIV status in the past 3 months were predictive of enrollment.

Conclusion—High notional acceptability suggests feasibility for contraceptive intravaginal ring use. Factors associated with ring use initiation and 6-month use will need to be assessed.

Keywords

Women; reproductive health; contraceptive intravaginal ring; Kenya; biomedical technology; sexual behavior; pregnancy; HIV and STI prevalence

Introduction

An integrated sexual and reproductive health approach, with emphasis on multipurpose prevention technologies (MPTs), is believed to offer the best solution for addressing women's needs [1]. Among the multiple MPTs under development, intravaginal rings (IVRs) have tremendous potential for preventing pregnancy, HIV, and other sexually transmitted infections (STIs) [2]. Only two IVRs are licensed for contraceptive use, neither of which are available currently in Kenya. Acceptance of and ability to correctly and consistently use IVRs in this setting are largely unknown.

Vaginal delivery of hormonal contraceptives and antimicrobials avoids the need for daily administration, circumvents systemic absorption, limits required doses by avoiding hepatic first-pass metabolism, and can be used by women discreetly [3]. Correct and consistent IVR use, however, may be threatened by complex cultural, behavioral, physiological, physical, interpersonal, and structural issues that may not be recognized or are acknowledged but downplayed during clinical development [4–6]. Such factors include, but are not limited to, sexual practices, intravaginal hygiene and menstruation practices, side effect concerns or experiences, willingness to disclose use to others, reproductive intentions, partner support, vaginal comfort, interference during intercourse, hormonal side effects (nausea, headaches,

gastrointestinal symptoms, vaginal discharge), the ring getting lost in the body [7–10], and IVR properties (e.g., method of insertion, duration of use, color, smell, size) [11].

Studies of NuvaRing, a one-month, low-dose etonogestrel and ethinyl estradiol-based ring, and other IVRs in development have suggested high product acceptability [7, 8, 10, 12–14] with user satisfaction centered on a woman being able to control ring insertion and removal, absence of remembering to take a daily pill, and comfort and ease of use [15].

A fundamental question in introducing MPT IVRs is whether women in developing countries are interested in such a product and its intended use(s). In this paper, we examined factors associated with enrolling in a study of NuvaRing use and describe notional acceptability of a contraceptive IVR (i.e., willingness to use a product solely based on information received about it).

Material and Methods

Design

Between April and November 2014, we enrolled women in a single group observational study of NuvaRing. Our research design included a pre-product phase ranging from 1 to 3 months (based on oral or injectable contraceptive use at enrollment) that was followed by 6 months of NuvaRing use, a one month post-product phase during which women returned to oral, injectable, or another contraceptive method of their choice, and then exited the study. For this analysis, we focused exclusively on screening data.

A multidisciplinary team of recruiters, data collectors, HIV test counselors, and study clinicians culturally similar to the target population and fluent in the three languages primarily spoken in the area (i.e., English, Kiswahili, and Dholuo) oversaw implementation of the study. The study staff was predominately comprised of women. All pelvic examinations were performed by female clinicians.

Ethical Review

Review and approval of the study protocol, consent forms, and data collection instruments was completed by the Scientific Steering and Ethical Review Committees of the Kenya Medical Research Institute, and an Institutional Review Board for the United States (US) Centers for Disease Control and Prevention. This trial is registered with ClinicalTrials.gov number NCT02529683.

Written informed consent was completed by women in their language preference before participating in data and specimen collections. Women who completed the in-depth screening process received a bar of soap, 500 Kenya Shillings (approximately $5 [US] dollars) for transport, feminine sanitary pads, and a treated malaria bed net. No incentives were provided for the pre-screening eligibility assessment conducted in the recruitment venues.

Using convenience sampling, women were recruited from family planning and reproductive health clinics, via 10 community health workers, and participant word-of-mouth referrals

without incentives. Based on initial community feedback, an overview of the study was presented to women in groups as opposed to approaching women individually. Women received information on the study, its purpose, and the risks and benefits of an IVR. They were shown a sample of the ring, allowed to visually and manually inspect it, and a 3-dimensional female reproductive model was used to demonstrate ring insertion and removal.

Eligibility and Data Collection

A two-step screening process (pre-screening and screening) was used. After privately obtaining pre-screening written informed consent and being assigned a unique study identification number, recruitment staff administered a brief pre-screening computer-assisted personal interview (CAPI). A woman was eligible to proceed with screening if she was 18 to 34 years of age, lived within 150 kilometers of Kisumu City, was sexually active in the past three months on more than one occasion, had used injectable depot medroxy-progesterone acetate (DMPA) or oral contraceptive pills (OCPs) in the past three months, and had never received an HIV-positive test result. Women also had to report willingness to switch from their existing birth control method to using NuvaRing for six months, to undergo periodic pelvic examinations and testing for pregnancy, HIV and other STIs, and to provide family clinic documentation of DMAP or OCP use in the past 3 months, as well as standard national documentation of age (e.g., identify card, birth notification/certificate).

Eligible women scheduled for a clinic screening visit, in which they presented the aforementioned documents and completed a second, more comprehensive written-informed consent that covered study risks, benefits, participant requirements, and procedures specifically related to screening and the pre-product phase. Detailed contact information was gathered and demographic, psychosocial, and behavioral information collected using audio computer-assisted self-interview (ACASI). A study clinician administered a medical evaluation CAPI and performed a general physical examination as well as a pelvic examination. A female 3-dimensional reproductive model was used to describe and demonstrate what would happen during the pelvic examination, and concerns were addressed before initiating the examination. Venous blood, urine, saliva and cervicovaginal lavage specimen collection was undertaken to test for pregnancy, HIV, herpes simplex virus type 2 (HSV-2), gonorrhea, syphilis, chlamydia, and bacterial vaginosis (BV). Verification that there were no pre-existing reproductive tract conditions was done through hematological and biochemistry analysis (e.g., cervical cancer visual inspection screening was completed using acetic acid and Lugol’s iodine). Rapid HIV testing was performed with pre- and post-test counselling and results provided according to Kenyan Ministry of Health guidelines [16]. Women were encouraged but not required to disclose potential study participation to sexual partners.

A follow-up appointment was made within two weeks of the screening visit to permit clinical staff to review laboratory results and make a final study eligibility determination. Women were not eligible to participate if they were found to have current or a history of known medical contraindications for NuvaRing use (e.g., thrombophlebitis or thromboembolic disorders, cerebral vascular or coronary artery disease, valvular heart disease with thrombogenic complications, severe hypertension, diabetes with vascular

involvement, headaches with focal neurological symptoms), to be breastfeeding or within three months of parturition, or tested positive for HIV. Women who tested HIV positive were provided additional counseling, underwent CD4 and viral load testing, and referred to a patient support center for appropriate HIV care and treatment services. Women who tested positive for gonorrhea, syphilis, or chlamydia were provided treatment and encouraged to invite their sexual partners to come for STI management and treatment [16]. Eligible women who declined study participation were asked to complete a refusal CAPI questionnaire.

Measures

Enrollment status (1 = enrolled, 0 = not enrolled) was our outcome. ACASI demographic variables included age group, ethnic/tribal group, marital status, religion, highest level of education completed, employment status, main source of income, and number of children in the household.

Notional acceptability, with dichotomous scores (1 = yes, 0 = no), was based on the CAPI pre-screening question, *Are you willing to change from <current contraceptive method> to using a vaginal ring to avoid or delay pregnancy?* Notional acceptability was viewed as pre-product use acceptance given that actual product use would be undertaken 1–3 months post enrollment as opposed to hypothetical willingness, in which intentionality may not be specific to a particular product (brand or formulation) or future timeframe. Notional acceptability was operationalized as willingness to use NuvaRing after receiving detailing information about it, being given the opportunity to visually and manually inspect the ring, and being shown how it was inserted and removed using a 3-dimensional female reproductive model.

Psychosocial variables, with dichotomous scores (1 = yes, 0 = no), were based on questions on motivations for participation, pregnancy intentions/desires, contraception use barriers, and willingness to undergo periodic testing for pregnancy, HIV, and other STIs. Pelvic exam acceptance items adopted from Fiddes and colleagues [17] were rated on a 5-point Likert scale (1 = strongly agree, 2 = agree, 3 = undecided, 4 = disagree, and 5 = strongly disagree) and a participant-level mean score was generated. The response scale for four negatively worded items (find pelvic exam unpleasant but can tolerate, anxious about the pelvic exam, distressed about the pelvic exam, would refuse the pelvic exam if offered) was reversed before scoring. Higher mean scores indicated less acceptance of/greater concern about pelvic exams. Cut-points for pelvic exam acceptance categories were derived from the quartiles for the pelvic exam measure (mean = 2.8 and median = 3.0; minimum = 0.7 and maximum =4.5; lower quartile = 2.7 and upper quartile = 3.0). Three acceptance cut-points (mean score ≤ 2.7 =high acceptance, mean score 2.7–2.99 = medium acceptance, and mean score ≥ 3 =low acceptance) were established.

Behavioral variables were age at sexual debut, number of sex partners (lifetime and in the past 3 months), history of forced sex, HIV-positive partner in the past 3 months, partner of unknown HIV status in the past 3 months, exchange sex in the past 3 months, vaginal or anal sex in without a condom in the past 3 months, history of having sex during menses, past history of STI diagnosis, alcohol use in the past 30 days, ever used drugs for recreational

purposes, abnormal vaginal bleeding in the past 12 months, and past medication-taking history. Laboratory results for pregnancy, HIV, and STIs were also included.

Statistical Analysis

We computed frequency counts and percentages to describe the demographics, psychosocial, and behavioral characteristics of women screened. In a univariable analysis, we compared enrollment status across groups of categorical predictors using prevalence ratios obtained from a log-binomial regression model. Adjusted effect estimates with 95% robust confidence intervals were obtained in a multivariable Poisson regression using the generalized estimating equations (GEE) approach. We employed backward elimination procedure with a 0.2 threshold level to select covariates in multivariable regression. All analyses were performed in SAS 9.3 (SAS Institute Inc., Cary, NC, USA).

Results

Pre-screeners

Among the 692 women pre-screened, 634 (91.6%) were found to be eligible to continue with the in-depth screening. Approximately 97% of pre-screened women were willing to switch from their current contraceptive method to NuvaRing for six months. As shown in Figure 1, the three most common reasons for pre-screening ineligibility were reluctance to switch to NuvaRing, not engaged in >1 episode of vaginal intercourse on different days in the past 30 days, and self-reported positive HIV status. Among the eligible pre-screened women, 26.9% were screening visit no-shows. During re-contact attempts, some women told recruiters that they were concerned about partner support, discovery of the ring during sexual intercourse, and pain or discomfort associated with pelvic examinations.

Screeners

Out of 463 (73.0%) women who completed the screening visit, three declined further study consideration. After meeting all eligibility criteria, 302 (99.3 %) of 304 women were enrolled into the pre-product phase of the study. Among women not eligible to take part in the study, reasons included testing positive for HIV (67/39.1%), lack of OCP/DMPA documentation (39/22.8%), body mass index >29.0 (34/19.9%), currently breastfeeding or within three months of parturition (9/5.3%), and laboratory confirmed pregnancy (8/4.7%). Among enrollees, 54 (17.9%) were OCPs users and 248 (82.1%) were DMPA users.

Almost all (90.9%) of the 463 screened were Luo, and 47.3% were between 18 and 24 years old, with a mean/median age of 25 (standard deviation 4.2) (Table 1). Approximately 63% reported being employed, 55.7% reported salary-based earnings as a main source of income, 68.2% had a primary education or lower, 44.8% were Roman Catholic, and 67.9% were married or cohabitating. The mean number of live births was 2.5 (median 2.0; range: 0–8) with approximately 45% reporting that they had three or more live births.

As shown in Table 2, the three most common motivations for joining the study were to learn: about modern family planning methods (99.1%), how to avoid HIV risk behaviors/behavior change (82.9%), and about causes of HIV (79.5%). In the bivariate analysis, women who did

not report free medical care for STIs as a motivator were less likely to be enrolled (prevalence ratio [PR] = 0.84, 95% confidence interval [CI] =0.73–0.97) than those enrolled. Women who reported wanting to learn how to avoid HIV risk behaviors as a motivator were less likely to be enrolled (PR 0.85, 95% CI 0.73–0.99) than those enrolled. Regardless of enrollment status, receiving incentives was the least common motivator overall, with 31% of women screened reporting that they were interested in joining the study for this reason.

Overall, less than 10% reported that they had desired or wanted to get pregnant within the next 12 months: 7.0% indicated that they wanted to be pregnant in the next 12 months and 9.6% planned to get pregnant in the next 12 months. Slightly over 13% responded that their partner wanted them to get pregnant in the next 12 months. Few barriers to using modern contraceptives were identified. Barriers predominately centered on concerns regarding access (17.6%), affordability (15.5%), and side effects (15.0%). Approximately a quarter (25.2%) reported that they had used two or more birth control methods over the past 12 months (Table 3). No significant difference in acceptance of pelvic exams was observed between women enrolled and women not enrolled. Overall, 51.3% scored medium acceptance of pelvic examinations.

Most of the women (90.8%) reported ever being pregnant (Table 3). Overall, prevalence was 1.7% for pregnancy, 14.5% for HIV, and 70.4% for other STIs. Sexual debut before the age of 17 was reported by 54.8%. While no statistical differences were observed between those enrolled and not enrolled, 34.6% of women screened reported experiencing physically forced sex at some point in their lives. Women who reported a single lifetime sexual partner (PR 1.34, 95% CI 1.07–1.67) or those reporting 2–3 lifetime sexual partners (PR =1.23, 95% CI 1.02–1. 59) were more likely to be enrolled than those who reported four or more lifetime partners Women who reported a single sexual partner in the past three months (PR 1.42, 95% CI 1.07–1.88) were more likely to be enrolled than those who reported two or more sexual partners in the past 3 months. While data were collected separately for vaginal and anal sex in the past 12 months, we combined these variables given that the prevalence for anal intercourse in the past 12 months for all women who completed the screening ACASI was 7.3%. Incidentally, 33 out of 34 women reporting anal intercourse in the past 12 months reported that condoms were not used. Overall, 91.9% engaged in vaginal or anal sex without a condom in the past three months. Women using DMPA in the past 12 months were more likely to be enrolled (PR = 1.36, 95% CI 1.09–1.69).

In the multivariable model, enrollment was significantly ($p < 0.05$) more likely among women who were aged 18–24 years old, married/cohabitating, reported sexual debut at less than 17 years of age, had one lifetime sexual partner, abnormal vaginal bleeding in the past 12 months, vaginal or anal sex without a condom in the past three months, and did not have a sexual partner of unknown HIV status in the past three months. DMPA use in the past 12 months was not significant in the multivariable model. (Table 4).

Discussion

This study successfully recruited and enrolled women for the pre-product use phase of a contraceptive IVR study in Kisumu, Kenya. Approximately for every five women pre-

screened, two were enrolled in our study. Multivariable regression analysis showed that enrollment was significantly higher among women who: were less than 25 years of age, reported a single lifetime sexual partner, did not have a recent partner of unknown HIV status, had experienced sexual debut before the age of 17, and had abnormal vaginal bleeding in the past 12 months.

Only about 1 out of 4 women uses a modern contraceptive method in sub-Saharan Africa [18]. Reproductive age accounts for some differences in contraceptive method choice and motivations for use. Data collected between 2004 and 2010 in 18 sub-Saharan African countries showed that the use of modern contraceptives to limit births was highest among women 35 years of age and older, while contraceptive use to space births was characteristic of women 25–29 years of age [18]. Younger women in our study may have been more interested in trying new technologies, especially short-term methods to space births. Cultural expectations for young married women to have children sooner rather than later [19] as well as beliefs regarding “having the right number of children” [20] could influence method choice, especially preferences that minimize detection of use by others or lessen inabilities to conceive when use of a method has stopped.

Early initiation of sexual intercourse (marital as well as premarital) among women has been shown to be associated with either low [21] or erratic [22] contraceptive use, including lower condom use to protect against HIV and other STIs. In our study, women with an age of sexual debut less than 17 years may have been more interested in taking part in the study because they had probably already experienced at least one pregnancy and were either using OCPs or DMPA. Since we did not enroll contraceptive-naïve women, it is unknown if their interest in an IVR would differ.

While women with one lifetime sexual partner and those who did not have a recent partner of unknown HIV status were at lower risk for HIV, their risk for unintended pregnancy and possibly unsafe abortions is unknown. The literature shows that women are more likely to forgo condom use given concerns about intimacy and trust with a main partner [23]. A recent qualitative study found that condoms were not considered as contraception by young Kenyan women [24]. Moreover, the perception that contraceptive use, including condom use, contribute to disease, promiscuity, and infidelity has been suggested in several studies [24–26].

Studies on the optimal ratio of women enrolled to those screened for IVRs and other contraceptive technologies are sparse; thus, making it somewhat difficult to ascertain if our enrollment to screening ratio (ESR) was high or low. In Cameroon, a preventive HIV/STI trial of a vaginally inserted nonoxynol 9 showed a 57.5% ESR (1317 enrolled among 2290 screened) [27]. The US-based Contraceptive CHOICE Project, which examined choice of free reversible contraceptive, suggested a 60.9% ESR (2500 enrolled out of 4107 screened) [28]. While the ESR is somewhat higher in these other studies, important contextual factors need to be taken into account for our sample (e.g., novelty of IVR, modern contraceptive use prevalence, potential inability to keep partner from knowing about IVR use). In addition, it is possible that our eligibility screening criteria may have affected our ESR by excluding women who were HIV-infected or unable to provide documentation of DMAP or OCP use.

While high pre-use, information-only-based acceptance of an IVR is suggested, caution must be taken in interpreting our findings, especially given that willingness to switch to NuvaRing was a study eligibility criterion. At most, our findings may suggest that the availability of a new contraceptive option was appealing to women in our sample. This is further supported by results that showed that learning about modern family planning was the most common motivator for seeking study participation. In addition, concerns with abnormal vaginal bleeding in the past 12 months that may have been associated with the contraceptive method reported at screening, especially DMPA [28], may have influenced women's willingness to try a new method. We acknowledge that the NuvaRing information provided during the screening process, while thorough, does not provide sufficient insights on readiness and acceptance. The concept of acceptability consists of two components: (a) willingness, which gets at mental readiness or inclination to try a product in the future or to recommend its use to others, and (b) use, which transforms intentions into actual experience that usually involves following prescribed instructions for correct and consistent use of a product or product substitute [29]. Women pre-screened for our study reported high NuvaRing notional acceptability. An accurate assessment of contraceptive IVR acceptability will be dependent on completion of all phases of the study.

We observed high prevalence of HIV, HSV-2, and BV. The Government of Kenya has identified Kisumu as one of the top three counties with a hyper-endemic HIV burden, with prevalence among women slightly higher than that of all of Kenya (20.3% versus 19.3%, respectively) and the median age of HIV acquisition significantly younger among women than men [30]. The literature shows that HSV-2 and BV are significantly associated with a risk for acquiring HIV [31], that HSV-2 increases the risk for BV [32], and that prevalent and incident HSV-2 infection is linked to an increased prevalence of BV [33–35]. A comprehensive approach to women's sexual and reproductive health would be of benefit in this setting.

We found a slightly higher percentage of women who reported sexual debut before the age of 15 than was reported in the 2011 Nyanza Province Multiple Indicator Cluster Survey (22.9% vs. 18.9%), which may be attributed to our suvery administration mode (ACASI vs. face-to-face interviewer-administered survey) or the age of our participants (18–34 years vs. 15–24 years) [36]. The evidence linking early sexual debut and lifetime risk for HIV infection for women in sub-Saharan Africa is conflicting. A systematic review showed a significant bivariate association between early sexual debut and HIV in higher quality studies, while other studies found either that later risky sexual behavior instead contributed to infection risk, or that increased infection was explained by biological factors, including genital trauma at sexual debut resulting from physically forced sex [37].

A number of limitations are associated with this study. Due to convenience sampling, women in our study may not be representative of women 18–34 years of age living in Kisumu County; generalizability is an issue. We focused on women already using DMPA and OCPs; thus, it is unknown if women using other contraceptive methods or those without prior contraceptive use experience may have characteristics that differ from our sample. Our findings can only provide insights regarding women's notional acceptance of a contraceptive IVR; subsequent analyses are required to examine actual use and adherence. While women

neither received eligibility criteria in advance of pre-screening nor were given specific reasons for ineligibility, there is the possibility that their overwhelming willingness to switch to the ring at pre-screening was influenced by social desirability. In addition, some women may have recognized or learned from others that willingness to use the ring was an eligibility requirement and that by providing a “yes” response this would help increase the likelihood that they would get into the study. Our recruitment method, while consistent with strategies for informing the community about happenings, may have prompted women to present for pre-screening to avoid drawing attention to them by responding differently than their peers. It may have also minimized peer speculations regarding a woman’s pregnancy or HIV status.

Conclusion

High notional acceptance suggests feasibility for contraceptive IVR use. Factors associated with actual ring will use need to be assessed. To address the high HIV and STI prevalence among young women in this setting, the co-formulation of hormonal contraception with antimicrobials may have enhanced uptake compared to rings for either indication alone.

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Abbreviations

ARV	Antiretroviral
CI	Confidence interval
DMPA	Depot medroxy-progesterone acetate
ESR	Enrollment to screening ratio

FEM-PrEP	Pre-exposure Prophylaxis Trial for HIV Prevention among African Women
HIV	Human Immunodeficiency Virus
HSV-2	Herpes simplex virus type 2
IVRs	Intravaginal rings
MPTs	Multipurpose prevention technologies
OCP	Oral contraceptive pill
PR	Prevalence Ratio
STIs	Sexually transmitted infections
TDF/FTC	Tenofovir/emtricitabine
US	United States
VOICE	Vaginal and Oral Interventions to Control the Epidemic Trial

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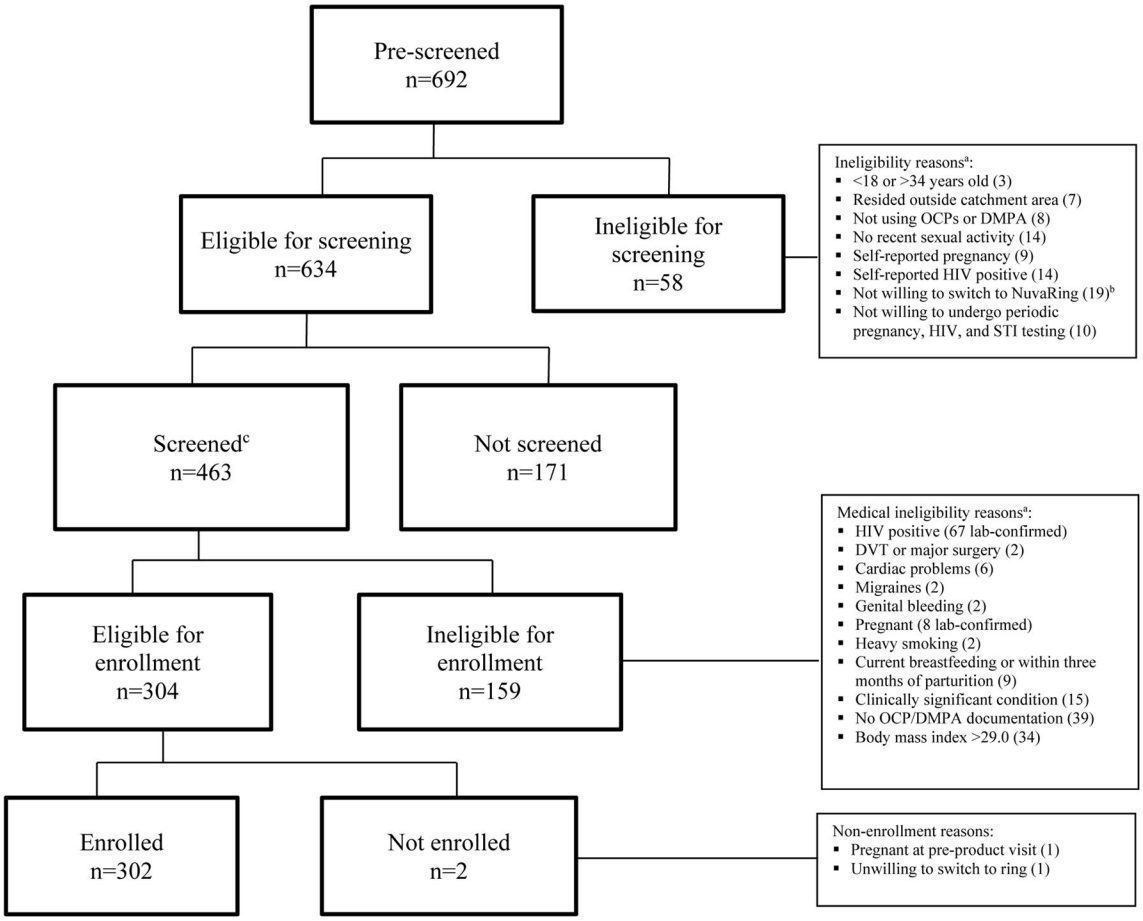

Figure 1. Flowchart: Screening and Enrollment, Kisumu Ring Study, 2014

[a]Possibly ineligible for multiple reasons.

[b]Five out of the 19 also declined further screening consideration, completed refusal questionnaires, and indicated unwillingness to switch to using the ring.

[c]Partial data available for five screeners: technical issues resulted in ACASI data loss for two screeners (only CAPI pre-screening and medical assessments were available). One of the two, met full enrollment criteria and was enrolled; and three screeners, completed the ACASI, but declined the medical assessment. None of the three were enrolled.

Table 1

Demographic Characteristics of Women Screened by Enrollment Status (n=463), Kisumu Ring Study, 2014

Variable Level	Total (N=463) n (%)	Enrolled (N=302) n (%)	Not Enrolled (N=161) n (%)	Enrolled Prevalence	Prevalence Ratio (95% CI)	p-value
Age at screening						0.003 *
18–24	219 (47.3)	159 (52.6)	60 (37.3)	72.6	1.47 (1.15, 1.88)	0.002
25–29	169 (36.5)	106 (35.1)	63 (39.1)	62.7	1.27 (0.98, 1.64)	0.067
30–34	75 (16.2)	37 (12.3)	38 (23.6)	49.3	Ref.	
Ethnic/tribal group						0.565
Luo	418 (90.9)	271 (90.3)	147 (91.9)	64.8	0.94 (0.76, 1.16)	0.565
Non-Luo	42 (9.1)	29 (9.7)	13 (8.1)	69.0	Ref.	
Marital status						0.001 *
Single	81 (17.9)	48 (16.3)	33 (20.9)	59.3	1.35 (0.97, 1.89)	0.073
Married/cohabiting	307 (67.9)	218 (74.1)	89 (56.3)	71.0	1.62 (1.22, 2.16)	0.001
Separated/Divorced/Widowed	64 (14.2)	28 (9.5)	36 (22.8)	43.8	Ref.	
Religion						0.989
Roman Catholic	206 (44.8)	135 (45.0)	71 (44.4)	65.5	1.01 (0.84, 1.22)	0.886
Other Christian	172 (37.4)	112 (37.3)	60 (37.5)	65.1	1.01 (0.83, 1.22)	0.940
Other non-Christian	82 (17.8)	53 (17.7)	29 (18.1)	64.6	Ref.	
Highest education completed						0.817
Primary or less[a]	313 (68.2)	205 (68.6)	108 (67.5)	65.5	0.97 (0.74, 1.26)	0.817
Secondary or more	146 (31.8)	94 (31.4)	52 (32.5)	64.4	Ref.	
Employment status						0.346
Employed	291 (63.4)	185 (61.9)	106 (66.3)	63.6	0.94 (0.82, 1.07)	0.346
Unemployed	168 (36.6)	114 (38.1)	54 (33.8)	67.9	Ref.	
Main source of personal income						0.026 *
None	22 (4.8)	12 (4.0)	10 (6.3)	54.5	0.75 (0.51, 1.11)	0.154
Salary-based	256 (55.7)	157 (52.2)	99 (62.3)	61.3	0.85 (0.74, 0.97)	0.013
Not salary-based	182 (39.6)	132 (43.9)	50 (31.4)	72.5	Ref.	
Number of live births[b]						0.433
0–2	245 (54.6)	166 (55.9)	79 (52.0)	67.8	1.60 (0.92, 1.21)	0.433

Variable Level	Total (N=463) n (%)	Enrolled (N=302) n (%)	Not Enrolled (N=161) n (%)	Enrolled Prevalence	Prevalence Ratio (95% CI)	p-value
3+	204 (45.4)	131 (44.1)	73 (48.0)	64.2	Ref.	

Sample sizes fluctuate slightly for some variables due to missing data. Some percentages do not sum to 100 because of rounding.

[a] 17 reported no schooling; 136 reported attending, but not completing primary education; 160 completed primary education.

[b] 51 reported one or more miscarriages/abortions (range: 1–7); and 6 reported still births (range: 1–2).

[*] Variable met p-value ≤.20 criteria for inclusion in the multivariable analysis.

Table 2

Psychosocial Characteristics of Women Screened by Enrollment Status (n=463), Kisumu Ring Study, 2014

Variable Level	Total (N=463) n (%)	Enrolled (N=302) n (%)	Not Enrolled (N=161) n (%)	Enrolled Prevalence	Prevalence Ratio (95% CI)	p-value
Motivations for participation:						
Receive free HIV testing and counseling						0.934
Yes	316 (69.0)	206 (69.1)	110 (68.8)	65.2	1.01(0.87, 1.16)	0.934
No	142 (31.0)	92 (30.9)	50 (31.3)	64.8	Ref.	
Receive free medical care for STIs and common illnesses						0.015 *
Yes	356 (77.9)	222 (74.7)	134 (83.8)	62.4	0.84 (0.73, 0.97)	0.015
No	101 (22.1)	75 (25.3)	26 (16.3)	74.3	Ref.	
Receive incentives						0.328
Yes	141 (31.1)	96 (32.7)	45 (28.3)	68.1	0.93 (0.79, 1.08)	0.328
No	312 (68.9)	198 (67.3)	114 (71.7)	63.5	Ref.	
Learn about causes of HIV						0.330
Yes	364 (79.5)	233 (78.2)	131 (81.9)	64.0	1.17 (0.84, 1.63)	0.330
No	94 (20.5)	65 (21.8)	29 (18.1)	69.1	Ref.	
Be able to share with others information learned about HIV						0.134 *
Yes	314 (68.9)	197 (66.6)	117 (73.1)	62.7	0.90 (0.78, 1.00)	0.134
No	142 (31.1)	99 (33.4)	43 (26.9)	69.7	Ref.	
Help in controlling the spread of HIV						0.158 *
Yes	359 (78.4)	228 (76.5)	131 (81.9)	63.5	0.90 (0.77, 1.04)	0.158
No	99 (21.6)	70 (23.5)	29 (18.1)	70.7	Ref.	
Learn how to avoid HIV risk behaviors						0.036 *
Yes	378 (82.9)	239 (80.5)	139 (87.4)	63.2	0.85 (0.73, 0.99)	0.036
No	78 (17.1)	58 (19.5)	20 (12.6)	74.4	Ref.	
Learn about modern family planning methods						
Yes	454 (99.1)	294 (98.7)	160 (100.0)	64.8		
No	4 (0.9)	4 (1.3)	0 (0.0)	100.0	Ref.	
Pregnancy desires/intentions						
Pregnancy desired t in the next 12 months						0.747

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Variable Level	Total (N=463) n (%)	Enrolled (N=302) n (%)	Not Enrolled (N=161) n (%)	Enrolled Prevalence	Prevalence Ratio (95% CI)	p-value
Yes	32 (7.0)	20 (6.7)	12 (7.5)	62.5	0.96 (0.72, 1.26)	0.747
No	425 (93.0)	278 (93.3)	147 (92.5)	65.4	Ref.	
Pregnancy planned in the next 12 months						0.396
Yes	44 (9.6)	31 (10.4)	13 (8.1)	70.5	1.09 (0.89, 1.34)	0.396
No	414 (90.4)	267 (89.6)	147 (91.9)	64.5	Ref.	
Partner wants her pregnant in the next 12 months						0.133 *
Yes	59 (13.1)	43 (14.7)	16 (10.2)	72.9	1.14 (0.96, 1.36)	0.133
No	390 (86.9)	249 (85.3)	141 (89.8)	63.8	Ref.	
Barriers to Modern Contraceptive Method Use						
Too difficult to get						0.230
Yes	76 (17.6)	45 (15.8)	31 (20.8)	59.2	0.88 (0.72, 1.08)	0.230
No	357 (82.4)	239 (84.2)	118 (79.2)	66.9	Ref.	
Unable to afford						0.230
Yes	67 (15.5)	39 (13.7)	28 (18.8)	58.2	0.87 (0.70, 1.08)	0.230
No	366 (84.5)	245 (86.3)	121 (81.2)	66.9	Ref.	
Unsure how to use desired method						0.811
Yes	20 (4.6)	14 (4.9)	6 (4.0)	70.0		
No	413 (95.4)	270 (95.1)	143 (96.0)	65.4	Ref.	
Afraid of side or bad effects						0.653
Yes	65 (15.0)	41 (14.4)	24 (16.1)	63.1	0.96 (0.78, 1.17)	0.653
No	368 (85.0)	243 (85.6)	125 (83.9)	66.0	Ref.	
Partner will/might disapprove						0.592
Yes	36 (8.3)	25 (8.8)	11 (7.4)	69.4	1.06 (0.85, 1.34)	0.592
No	397 (91.7)	259 (91.2)	138 (92.6)	65.2	Ref.	
Community will/might disapprove						0.548
Yes	2 (0.5)	2 (0.7)	0 (0.0)	100.0		
No	431 (99.5)	282 (99.3)	149 (100.0)	65.4	Ref.	
Church/religious community might disapprove						0.170 *
Yes	5 (1.2)	5 (1.8)	0 (0.0)	100.0		
No	428 (98.8)	279 (98.2)	149 (100.0)	65.2	Ref.	

Variable Level	Total (N=463) n (%)	Enrolled (N=302) n (%)	Not Enrolled (N=161) n (%)	Enrolled Prevalence	Prevalence Ratio (95% CI)	p-value
Want children						0.664
Yes	5 (1.2)	4 (1.4)	1 (0.7)	80.0		
No	428 (98.8)	280 (98.6)	148 (99.3)	65.4	Ref.	
Other barriers						1.000
Yes	5 (1.2)	3 (1.1)	2 (1.3)	60.0		
No	428 (98.8)	281 (98.9)	147 (98.7)	65.7		
None, nothing can prevent use						0.878
Yes	178 (41.1)	116 (40.8)	62 (41.6)	65.2	0.99 (0.861.14, 1.33)	0.878
No	255 (58.9)	168 (59.2)	87 (58.4)	65.9	Ref.	
Study Procedures Acceptance						
Switch NuvaRing for 6 months (notional acceptability)						
Yes	463 (100.0)	302 (100.0)	161 (100.0)	100.0		
Undergo periodic testing for pregnancy, HIV and STIs						
Yes	463 (100.0)	302 (100.0)	161 (100.0)	100.0		
Routine pelvic exam						0.855
High	142 (31.0)	95 (31.9)	47 (29.4)	66.9	1.04 (0.85, 1.27)	0.685
Medium	235 (51.3)	151 (50.7)	84 (52.5)	64.3	1.00 (0.83, 1.21)	0.993
Low	81 (17.7)	52 (17.4)	29 (18.1)	64.2	Ref.	

Sample sizes fluctuate slightly for some variables due to missing data. Some percentages do not sum to 100 because of rounding.

*Variable met p-value ≤.20 criteria for inclusion in the multivariable analysis.

Table 3

Behavioral Characteristics of Women Screened by Enrollment Status (n=463), Kisumu Ring Study, 2014

Variable Level	Total (N=463) n (%)	Enrolled (N=302) n (%)	Not Enrolled (N=161) n (%)	Enrolled Prevalence	Prevalence Ratio (95% CI)	p-value
Reproductive and Sexual Health						
Age at sexual debut[a]						0.328
13 or less	77 (20.8)	50 (21.0)	27 (20.3)	64.9	1.33 (0.93, 1.91)	0.119
14–16	126 (34.0)	85 (35.7)	41 (30.8)	67.5	1.38 (0.98, 1.95)	0.064
17–19	129 (34.8)	84 (35.3)	45 (33.8)	65.1	1.34 (0.95, 1.89)	0.100
20+	39 (10.5)	19 (8.0)	20 (15.0)	48.7	Ref.	
Ever experienced physically forced sex						0.446
Yes	121 (34.6)	82 (36.0)	39 (32.0)	67.8	1.06 (0.91, 1.24)	0.446
No	229 (65.4)	146 (64.0)	83 (68.0)	63.8	Ref.	
# lifetime sexual partners						0.029*
1	60 (15.9)	44 (18.1)	16 (11.9)	73.3	1.34 (1.07, 1.67)	0.011
2–3	195 (51.7)	132 (54.3)	63 (47.0)	67.7	1.23 (1.02, 1.59)	0.029
4+	122 (32.4)	67 (27.6)	55 (41.0)	54.9	Ref.	
# partners in past 3 months						0.016*
1	272 (82.9)	186 (87.3)	86 (74.8)	68.4	1.42 (1.07, 1.88)	0.016
2+	56 (17.1)	27 (12.7)	29 (25.2)	48.2	Ref.	
HIV+ partner in the past 3 months						0.483
Yes	83 (27.7)	51 (26.3)	32 (30.2)	61.4	0.93 (0.77, 1.13)	0.483
No	217 (72.3)	143 (73.7)	74 (69.8)	65.9	Ref.	
HIV status unknown partners in past 3 months						0.118*
Yes	153 (50.5)	94 (47.2)	59 (56.7)	61.4	0.88 (0.75, 1.03)	0.118
No	150 (49.5)	105 (52.8)	45 (43.3)	70.0	Ref.	
Abnormal vaginal bleeding in the past 12 months						0.020*
Yes	100 (21.8)	74 (24.8)	26 (16.3)	74.0	1.18 (1.03, 1.36)	0.020
No	358 (78.2)	224 (75.2)	134 (83.8)	62.6	Ref.	
Exchange sex[b] in the past 3 months						0.923
Yes	48 (14.0)	31 (13.9)	17 (14.3)	64.6	0.99 (0.79, 1.24)	0.923

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Variable Level	Total (N=463) n (%)	Enrolled (N=302) n (%)	Not Enrolled (N=161) n (%)	Enrolled Prevalence	Prevalence Ratio (95% CI)	p-value
No	294 (86.0)	192 (86.1)	102 (85.7)	65.3	Ref.	
Vaginal or anal sex[c] without a condom in the past 3 months						0.197*
Yes	305 (91.9)	202 (93.5)	103 (88.8)	66.2	1.28 (0.88, 1.85)	0.197
No	27 (8.1)	14 (6.5)	13 (11.2)	51.9	Ref.	
Ever been pregnant						0.460
Yes	416 (90.8)	273 (91.6)	143 (89.4)	65.6	1.10 (0.85, 1.43)	0.460
No	42 (9.2)	25 (8.4)	17 (10.6)	59.5	Ref.	
Currently pregnant (self-report)						0.698
Yes	7 (1.5)	4 (1.3)	3 (1.9)	57.1		
No	450 (98.5)	294 (98.7)	156 (98.1)	65.3	Ref.	
Pregnancy test result						<0.001*
Positive	8 (1.7)	0 (0.0)	8 (5.0)	0.0		
Negative/Other	453 (98.3)	302 (100.0)	151 (95.0)	66.7	Ref.	
Number contraceptive methods past 12 months						0.005*
0	11 (2.4)	2 (0.7)	9 (5.6)	18.2		
1	334 (72.5)	223 (74.1)	111 (69.4)	66.8		
2+	116 (25.2)	76 (25.2)	40 (25.0)	65.5	Ref.	
Ever used female condom						0.192*
Yes	55 (12.0)	31 (10.4)	24 (15.0)	56.4	0.85 (0.67, 1.08)	0.192
No	403 (88.0)	267 (89.6)	136 (85.0)	66.3	Ref.	
Ever had sex during menses						0.256
Not applicable	65 (14.1)	39 (13.0)	26 (16.3)	60.0	0.84 (0.67, 1.06)	0.149
No	294 (63.9)	189 (63.0)	105 (65.6)	64.3	0.90(0.78, 1.05)	0.178
Yes	101 (22.0)	72 (24.0)	29 (18.1)	71.3	Ref.	
Ever had a STI[d] (self-reported)						0.574
Yes	109 (29.1)	74 (30.1)	35 (27.3)	67.9	1.05 (0.89, 1.22)	0.574
No	265 (70.9)	172 (69.9)	93 (72.7)	64.9	Ref.	
≥1 STI test results[d]						0.197*
Yes	321 (70.4)	204 (68.5)	117 (74.1)	63.6	0.91 (0.79, 1.05)	0.197
No	135 (29.6)	94 (31.5)	41 (25.9)	69.6	Ref.	

Variable Level	Total (N=463) n (%)	Enrolled (N=302) n (%)	Not Enrolled (N=161) n (%)	Enrolled Prevalence	Prevalence Ratio (95% CI)	p-value
HIV test result						<0.001 *
Positive	67 (14.5)	0 (0.0)	67 (42.1)	0.0		
Negative	394 (85.5)	302 (100.0)	92 (57.9)	76.6	Ref.	
Past medication adherence history (lifetime)						0.570
High	166 (36.4)	111 (37.2)	55 (34.8)	66.9	1.10 (0.91, 1.31)	0.328
Modest	177 (38.8)	118 (39.6)	59 (37.3)	66.7	1.09 (0.91, 1.31)	0.340
Low	113 (24.8)	69 (23.2)	44 (27.8)	61.1	Ref.	
Substance use						
Alcohol use in past 30 days						0.239
Yes	111 (24.0)	67 (22.2)	44 (27.3)	60.4	0.90 (0.76, 1.07)	0.239
No	352 (76.0)	235 (77.8)	117 (72.7)	66.8	Ref.	
Ever used drugs						0.825
Yes	27 (5.9)	17 (5.7)	10 (6.3)	63.0	0.97 (0.72, 1.30)	0.825
No	430 (94.1)	280 (94.3)	150 (93.8)	65.1	Ref.	

Sample sizes fluctuate slightly for some variables due to missing data. Some percentages do not sum to 100 because of rounding.

* Variable met p-value ≤.20 criteria for inclusion in the multivariable analysis.

[a] 22.9% reported first sex before the age of 15.

[b] Received gifts, money, food, shelter, cosmetics, other material goods, and/or services for providing sex.

[c] 34 women reported anal sex in the past 12 months; 33 out of the 34 indicated that a condom was not used.

[d] 54.9% tested positive for HSV-2, 3.9% for gonorrhea, 1.9% for syphilis, 4.5% for chlamydia, and 38.0% for bacterial vaginosis.

Table 4

Final Multivariable Model for Women Screened by Enrollment Status (n=289), Kisumu Ring Study, 2014

Variable Level	Total (N=289) n (%)	Enrolled (N=188) n (%)	Not Enrolled (N=101) n (%)	Prevalence of Enrolled	Adj. Prevalence Ratio (95% CI)	p-value
Age at screening						0.001
18–24	147 (50.9)	111 (59.0)	36 (35.6)	75.5	1.59 (1.16, 2.16)	0.003
25–29	94 (32.5)	56 (29.8)	38 (37.6)	59.6	1.24 (0.89, 1.73)	0.205
30–34	48 (16.6)	21 (11.2)	27 (26.7)	43.8	Ref.	
Marital status						0.002
Single	56 (19.4)	32 (17.0)	24 (23.8)	57.1	1.11 (0.75, 1.64)	0.610
Married/cohabiting	190 (65.7)	138 (73.4)	52 (51.5)	72.6	1.52 (1.08, 2.14)	0.016
Separated/Divorced/Widowed	43 (14.9)	18 (9.6)	25 (24.8)	41.9	Ref.	
Had abnormal vaginal bleeding in the past 12 months						0.036
Yes	59 (20.4)	47 (25.0)	12 (11.9)	79.7	1.21 (1.01, 1.44)	0.036
No	230 (79.6)	141 (75.0)	89 (88.1)	61.3	Ref.	
Age at sexual debut						0.067
13 or younger	57 (19.7)	42 (22.3)	15 (14.9)	73.7	1.58 (1.10, 2.27)	0.013
14–16	100 (34.6)	69 (36.7)	31 (30.7)	69.0	1.56 (1.09, 2.22)	0.015
17–19	98 (33.9)	62 (33.0)	36 (35.6)	63.3	1.38 (0.97, 1.97)	0.074
20+	34 (11.8)	15 (8.0)	19 (18.8)	44.1	Ref.	
# lifetime sexual partners						0.040
1	44 (15.2)	34 (18.1)	10 (9.9)	77.3	1.36 (1.07, 1.72)	0.012
2–3	152 (52.6)	105 (55.9)	47 (46.5)	69.1	1.21 (0.99, 1.48)	0.064
4+	93 (32.2)	49 (26.1)	44 (43.6)	52.7	Ref.	
Vaginal or anal sex without a condom in the past 3 months						0.046
Yes	265 (91.7)	176 (93.6)	89 (88.1)	66.4	1.43 (1.01, 2.02)	0.046
No	24 (8.3)	12 (6.4)	12 (11.9)	50.0	Ref.	
HIV status unknown partners in past 3 months						0.017
Yes	144 (49.8)	86 (45.7)	58 (57.4)	59.7	0.82 (0.70, 0.97)	0.017
No	145 (50.2)	102 (54.3)	43 (42.6)	70.3	Ref.	